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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,354	09/07/2006	Ralph P. Robinson	PC25529A	1679
25533 7590 08/01/2007 PHARMACIA & UPJOHN 7000 Portage Road KZO-300-104 KALAMAZOO, MI 49001				
			EXAMINER KUMAR, SHAIENDRA	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 08/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,354	ROBINSON ET AL.	
	Examiner	Art Unit	
	SHAIENDRA - KUMAR	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12 and 18 is/are allowed.
- 6) ☒ Claim(s) 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/14/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-18 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 7/14/06 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

2. Claims 13-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some inflammatory diseases, like asthma, arthritis, does not reasonably provide enablement for pelvic inflammatory, inflammatory bowel diseases, inflammatory thyroid diseases and also not enabled for neoplastic diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to how to make and use the invention commensurate in scope with these claims.

Applicants are claiming inflammatory diseases, which are very broad and also the pharmaceutical composition is being claimed for treating various disorders including neoplastic diseases. There is no support in the specification that instant claimed compounds can treat all types of cancers, as various cancers have different morphology, and there is no single compound that can treat all types of cancers.

3. Claims 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the Enablement is considered in view of the Wands factors (MPEP 2164.01 (a).

These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: Claims 13-17 are drawn to pharmaceutical composition for treating cancer and/or tumors broadly octahydrophenanthrene hydrazide in a mammal including a human.

Breadth of the claims: The complex nature of the claim greatly exacerbated by breadth of the claims. The claims encompass treating cancer and/or tumors broadly in a mammal including a human.

Guidance of the specification:

The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to treat cancers broadly. The guidance provided by the specification is directed to specific cancer in a specific concentration of the claimed compounds.

Working examples: All the working examples provided by the specification are directed to as to how to make the compounds.

State of the art: while the state of the art is relatively high with regard to treatment of specific cancers, the state of the art with regard to single agent for treating cancer broadly is underdeveloped. In particular, there is no known anticancer agent which is effective against all cancers. The Carter et al reference clearly teaches that for the forty known anticancer agents, none are effective against all cancers. Also, Smith et al suggests that expression of GR is related to breast cancer, but overall significance of these results are not fully clear.

Predictability of the art: the lack of significant guidance from the specification or prior art with regard to the actual treatment of all cancers in a mammal including humans subject with the claimed compounds makes practicing the claimed invention unpredictable.

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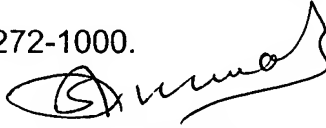
The quantity of experimentation necessary:

Applicants fail to provide guidance and information to allow the skilled artisan to ascertain which particular type of cancer the claimed anticancer agent is effective against without undue experimentation. The limited disclosure of several cancer is noted but will not support all cancers being claimed. The Carter et al reference shows data on twenty-three types of cancer. Applicants should at least test these types of cancer in mammals with the claimed anticancer agent.

4. Claims 1-12 and 18 are free of prior art and are allowable.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S. Kumar
7/27/07